Date: January 30, 2025

URGENT FIELD SAFETY NOTICE

Access Erythropoietin (EPO)
100 determinations, 2 packs, 50 tests/pack

REF	UDI**	LOT	⌛
A16364	15099590201838	439363	05-28-2025

Single Registration Number (SRN):** US-MF-000010288

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field safety corrective action for the product listed above. This letter contains important information that needs your immediate attention.

ISSUE:	Beckman Coulter has determined that the Access Erythropoetin (EPO) reagent lot number listed in the table above exhibits an approximate concentration bias of ~-22% with patient samples when compared to alternate EPO reagent lots.
IMPACT:	• Patient samples tested with the Access EPO reagent lot listed above may demonstrate repeatable falsely decreased results • Falsely decreased EPO results on patient samples could lead to improper diagnosis and/or repeat testing • Internal testing has shown that QC results do not illustrate the same concentration drop

ACTION:	• Discontinue using and discard all remaining reagent packs of the Access EPO reagent lot listed above.
	• Beckman Coulter recommends sharing the content of this letter with your laboratory and/or medical director regarding the need to review previous patient test results.
	• Contact your local Beckman Coulter representative for replacement product requests.
	  ○ For customers in the United States and Canada: Complete the attached replacement order form.
	  ○ For customers outside of the United States and Canada: Contact your local Beckman Coulter representative

RESOLUTION:	• Beckman Coulter is no longer distributing the Access EPO reagent lot listed in this letter. • Beckman Coulter is investigating the root cause of this issue.

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318, USA

phone: 952.448.4848
fax: 800.232.3828
www.beckmancoulter.com

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- From our website: http://www.beckmancoulter.com

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

Signed by:

Signer Name: Ian Pilcher
Signing Reason: I approve this document
Signing Time: 03-Feb-2025 | 5:11:30 PM PST
73C58D9A69DC485EA887E365533D3D7D

Ian Pilcher
Director Regulatory Affairs, Clinical Chemistry & Immunoassay

Enclosure: Response Form
Replacement Order Form

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318, USA

phone: 952.448.4848
fax: 800.232.3828
www.beckmancoulter.com

FA-25011